Message

From: Mendelsohn, Mike [Mendelsohn.Mike@epa.gov]

Sent: 5/5/2020 9:10:40 PM

To: McNally, Robert [Mcnally.Robert@epa.gov]; Overstreet, Anne [overstreet.anne@epa.gov]; Sadowsky, Don

[Sadowsky.Don@epa.gov]; Ingram, Earl [Ingram.Earl@epa.gov]

Subject: Fw: EPA and FDACS

Attachments: ATT00001.txt; EPA Letter re FDACS.pdf

Don,

This is the most recent email and letter we have regarding Oxitec allowing us to share information with FDACs.

Mike

From: Nathan Rose <nathan.rose@oxitec.com>

Sent: Tuesday, March 24, 2020 11:25 AM

To: Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>; Reynolds, Alan <Reynolds.Alan@epa.gov>; Bohnenblust, Eric

<Bohnenblust.Eric@epa.gov>

Cc: Kevin Gorman < Kevin.Gorman@oxitec.com>; Matthews, Keith < KMatthews@wiley.law>

Subject: EPA and FDACS

Dear Mike, Alan and Eric

Attached to this email is the letter that we discussed yesterday authorizing BPPD to discuss the Oxitec OX5034 EUP application with FDACS for purpose of facilitating the Florida State EUP application. As I mentioned during the call, we have concerns about the ability to protect CBI in Florida if FDACS receives Oxitec information from someone other than Oxitec. For that reason I have identified specific documents that I prefer FDACS receive from Oxitec, if it is requested by FDACS. If you have thoughts on this, or would like to discuss the list, we can be available at your convenience.

We spoke to FDACS yesterday regarding the current status of the application, and FDACS indicated that the best point of contact for them is Amy Brown, Chief of the Bureau of Scientific Evaluation & Technical Assistance at FDACS. Her email is amy.brown@fdacs.gov – any updates you can provide them on the application's progress would be very helpful to them.

As we mentioned on the call yesterday, finalizing the CSF is important to enable us to submit the state EUP. We're hoping to submit the state EUP by the end of this week, to allow FDACS to begin its formal review in parallel with EPA's ongoing review of the application. If there's any assistance or assurance that EPA can offer, to help us finalise the CSF, we'd really appreciate it. If FDACS can begin their formal review as soon as possible, it'll help to get into the field in 2020.

Thanks for your cooperation in helping Oxitec move forward with the Florida EUP.

Kind regards Nathan

Nathan Rose, DPhil Head of Regulatory Affairs Oxitec Ltd 71 Innovation Drive, Milton Park

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